

V 10 0313

1 of 2

510(k) Summary

DRAFT 9-27-2010

JUN 14 2011

Proprietary Name: *HydroFix™ Surgical Sheet*
Common Name: Surgical Sheet
Classification Name: 21 CFR § 878.3300, Surgical Mesh
Device Class: II
Product Code: FTL
Classification Panel: General & Plastic Surgery
Establishment Registration: 3006731846

Contact Person: Sally Thorsen
MiMedx Group, Inc.
811 Livingston Court SE, Suite B
Marietta, GA 30067
sthorsen@mimedx.com

Manufacturer: MiMedx Group, Inc.
811 Livingstone Court SE, Suite B
Marietta, GA 30067

Performance Standards:

Testing performed indicates the *HydroFix™ Surgical Sheet* is substantially equivalent to predicate devices.

Device Description:

The *HydroFix™ Surgical Sheet* is a flexible sheet of 30 Wt.% polyvinyl alcohol (PVA) material with dimensions 60 ±6 mm X 50 ±5 mm and 60 ±6 mm X 100 ±10 mm with a thickness of 1.0 ±0.2 mm. The corners of the sheet are rounded. There are no holes or perforations. There are no markings on either side of the sheet, raised (embossed) or printed. The sheet is provided sterile and hydrated in saline solution.

The *HydroFix™ Surgical Sheet* will be provided in other shapes and sizes as needed for particular surgical procedures.

Indications For Use:

The MiMedx *HydroFix™ Surgical Sheet* is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The surgical sheet minimizes tissue attachment to the device in case of direct contact with the tissues.

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Substantially Equivalent Device(s):

The following are substantially equivalent predicate devices.

K072190 *Mast Biosurgery, Ortho-Wrap Bioresorbable Sheet*

K090778 *Xylos Corporation, MTA Protective Sheet*

The MiMedx Group *HydroFix™ Surgical Sheet* was shown to be substantially equivalent to previously cleared device and has the same indications for use, design, function and/or materials.

Brief Comparison Summary:

To demonstrate substantial equivalence of the MiMedx *HydroFix™ Surgical Sheet* to the predicate devices, technological characteristics and performance criterion were evaluated using *in vitro* and *in vivo* testing as indicated below:

In Vitro Testing

- Suture Pull out
- Tensile Strength
- Burst Strength
- Tear resistance

The results of these tests demonstrate that the technological characteristics and performance criteria of the MiMedx *HydroFix™ Surgical Sheet* are comparable to the predicate devices and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

In Vivo Testing

To assess the performance of the MiMedx *HydroFix™ Surgical Sheet*, *in vivo* studies have been conducted in both sheep and rabbit models to evaluate the following attributes:

- Tissue attachment
- Ability to suture to tissue
- Ability to cut the sheet
- Ability to secure to tissue
- Ability to manage and protect tendon injuries

The results of these studies show the MiMedx *HydroFix™ Surgical Sheet* are comparable to predicate devices and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusion:

The sponsor believes that the data and information presented in this 510(k) application, including *in vitro* and *in vivo* testing, and numerous device similarities support a determination of substantial equivalence, and therefore market clearance of the MiMedx *HydroFix™ Surgical Sheet* through this 510(k).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

MiMedx Group
% Mr. William Jackson
VP, Regulatory Affairs and Quality Assurance
811 Livingston Court SE, Suite B
Marietta, GA 30067

JUN 14 2011

Re: K100313

Trade/Device Name: MiMedx *HydroFix*™ Surgical Sheet
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: June 2, 2011
Received: June 2, 2011

Dear Mr. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

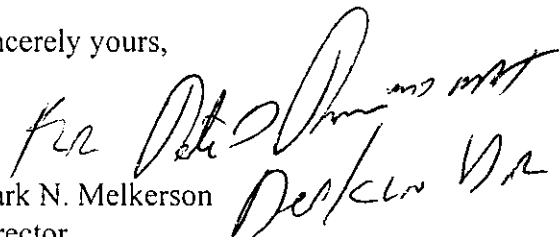
Page 2 - Mr. William Jackson

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100313

Device Name: **MiMedx *HydroFix™ Surgical Sheet***

The MiMedx *HydroFix™ Surgical Sheet* is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The surgical sheet minimizes tissue attachment to the device in case of direct contact with the tissues.

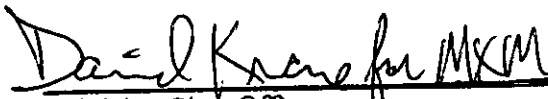
Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100313